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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,389	02/26/1999	KATIA GEORGOPOULOS	10287/043001	5245
26161	7590	06/02/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/259,389

Applicant(s)

GEORGOPOULOS ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 15, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,10,11,13,21 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,5,21,25-28 is/are allowed.
- 6) ☒ Claim(s) 3,10,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 15, 2004 has been entered.

DETAILED ACTION

This application filed March 26, 1999, claims benefit to provisional application 60/076,325, filed March 27, 1998.

Applicants' amendment filed March 15, 2004, has been received and entered. Claims 1, 4, 6-9, 12, 14-20 and 22-24 have been canceled. Claims 2, 5, 10, 11 and 21 have been amended. Claims 25-28 have been added. Claims 2, 3, 5, 10, 11, 13, 21 and 25-28 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 3, 10, 11 and 13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons below and set forth in the previous office action.

Applicants note the amendment to the claims, noting that claim 3 recites hybridization conditions and that the language is similar to that of Example 9 provided in the guidelines provided by the USPTO and is sufficient to meet the written description requirement under federal law, citing *Enzo Biochem, Inc. v. Gen-Probe Inc.* in support of their assertion. See Applicants' amendment page 5. Applicants' arguments have been fully considered, but not found persuasive.

Initially, it is noted that the amendments to claims 2, 5, 21 have obviated the basis of the rejection, and are no longer subject to the rejection. Also, newly added claims 25-28 encompass specific sequences and are not subject to the instant rejection. Finally, claims 10, 11 and 13 are included in the basis of the instant rejection solely because of their dependence on claim 3, and not because of their dependency to claims 2 nor 5.

Examiner notes that the claim has been amended so that the functional limitations are directed to the functional properties of the protein encoded by the polynucleotide. Claim 3 is now limited structurally in that it has a specific functionality by setting forth specific transcription factor functions. However, as noted in the previous office action, the functional limitations set forth in the instant claim is not specific to Helios, rather they are functions and/or activities which are exhibited by Helios, Aiolos and Ikaros polypeptides of the other family

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members. As taught in the present disclosure, the art of record and noted in the declaration of Dr. Georgopoulos, Helios is part of a family of highly related proteins and the functional limitations relied upon do not distinguish Helios from any other related family member. As supported by the findings in *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) because Helios is part of a family of highly related proteins functional limitations accorded to other family members would be considered adequate description (' It does not define any structural features commonly possessed by members of the genus that distinguish them from others. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.' citing *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06). Further, even if a detailed comparison of sequences and activities of the various family members would provide guidance for molecules lacking these sequences and that would fall outside the functional limitations of the claims, they do not describe the essential amino acids within these domains which are required or which amino acids which can be changed without affecting the function of the respective domain.

Since the functional limitations encompass other Ikaros family members it does not distinguish Helios by any of these specific activities recited. Any comparison or demonstration for the absence of functionally related domains only provides guidance for what is not encompassed by the claim, not a description of the sequences comprised by the claim. The specification provides only one species of the Helios protein claimed, SEQ ID NO: 6, and is silent to any other species among the large number of species encompassed by the sequences that would be identified by the hybridization conditions. Again, the specification fails describe any

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specific alteration of any of the specific domains which would result in an functional domain, rather it relies on what is not encompassed by the claim focusing on alterations which abolish activity. 'It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.' (See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")). Accordingly, naming a type of material generally believed to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. As noted in the previous office action, Examiner would not contest that some of the variant Helios proteins besides SEQ ID NO: 6 may have the activity recited in the claim and inherent to the Helios protein, however in view of the teachings of the instant specification, the artisan would not know if any given sequence were biological active or maintained the recited functions absent the empirical testing of said variant protein. Given that each of the Ikaros proteins have shared biological activities, the uniqueness of each of the family members should come from their differences in amino acid sequence. Besides a general comparison, the specification fails to clearly indicate which amino acids are necessary for any given activity or which ones can be changed without consequence to the activity.

Again, the functions recited and relied upon are shared among all Ikaros family members, the specification fails to provide adequate written description of the Helios gene product. As noted in the prior office actions, Hahm *et al.* point out that even though work to elucidate the role

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of Ikaros has been done, 'the specific functions of Helios and of the Helios-Ikaros complex remain unknown' and 'remain to be elucidated' (page 792; discussion). Kelly *et al.* state '[m]utational analysis of the Helios gene will help to dissect its role in regulating progenitor development in the hematopoietic system' (page 514; final paragraph), suggesting the function of Helios is not known, and that one can not relate changes in Helios expression or mutations. In light of the teaching in the present specification the invention encompasses many species of the Helios sequence and fragments which encode functional Helios protein. Examiner has acknowledged that hybridization can be used to identify related polynucleotides from other species of animals, the present claims encompass much more than this encompassing synthetically generated sequences, and unlike hybridization conditions used to identify other related species in nature the present claims encompass non-natural occurring sequences which clearly encompass sequences which have no function. They include fragments of Helios, and other variants comprising deletions, substitutions, insertions, additions, or replacements of Helios sequences other than those which may naturally occur in nature.

The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, the specification provides literal support for the recited

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embodiments, however the specification fails to describe the relevant identifying characteristics of any of the nucleic acid sequences of any of the sequences which result in a Helios protein with the biological activities recited in the claims besides SEQ ID NO: 6. One cannot describe what one has not conceived. (*Fiddes v. Baird*, 30 USPQ2d 1481, 1483). In the instant case, SEQ ID NO: 6 is the single known protein to meet the biological limitations set forth in the claims, however it is unclear which other variant Helios proteins, and more specifically, what particular alterations can be made to Helios within the full breadth of the claim without empirically testing each variant.

Conclusion

Claims 2, 5, 21 and 25-26 are allowed.

Claims 10, 11 and 13 rejected, however would be found allowable if rewritten in independent form encompassing all the embodiments of only claims 2 and 5.

Claim 3 is free of the art of record because the art fails to teach the polynucleotide sequences which would anticipate the present claims, however the claim is subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

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